

44931, August 31, 1994), EPA has determined that when used in accordance with good agricultural practice, this ingredient is useful and that the tolerances will protect the public health. Therefore, EPA is proposing to establish permanent tolerances as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 8F3658/P605]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12866. Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing exemptions from tolerance requirements do not have a significant impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 15, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By revising § 180.459, to read as follows:

§ 180.459 Triasulfuron; tolerances for residues.

Tolerances are established for residues of the herbicide triasulfuron, [3-(6-methoxy-4-methyl-1,3,5-triazin-2-yl)-1-(2-(2-chloroethoxy)phenylsulfonyl)urea] in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, forage	5.0
Barley, grain	0.02
Barley, straw	2.0
Cattle, fat	0.1
Cattle, kidney	0.2
Cattle, mbyp (except kidney)	0.1
Cattle, meat	0.1
Goats, fat	0.1
Goats, kidney	0.2
Goats, mbyp (except kidney)	0.1
Goats, meat	0.1
Hogs, fat	0.1
Hogs, kidney	0.2
Hogs, mbyp (except kidney)	0.1
Hogs, meat	0.1
Horses, fat	0.1
Horses, kidney	0.2
Horses, mbyp (except kidney) ..	0.1
Horses, meat	0.1
Milk	0.02
Sheep, fat8	0.1
Sheep, kidney	0.2
Sheep, mbyp (except kidney) ...	0.1
Sheep, meat	0.1
Wheat, forage	5.0
Wheat, grain	0.02
Wheat, straw	2.0

[FR Doc. 95-6417 Filed 3-14-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 4E4359/P604; FRL-4936-3]

RIN 2070-AC18

Pesticide Tolerance for Paraquat

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish tolerances for residues of the desiccant, defoliant, and herbicide paraquat in or on the raw agricultural commodities lentils, lentil forage, and lentil hay. The proposed regulation to establish maximum permissible levels for residues of the herbicide was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

DATES: Comments, identified by the document control number, [PP 4E4359/P604], must be received on or before April 14, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8783.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 4E4359 to EPA on behalf of the Agricultural Experiment Stations of Idaho and Washington. This petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.205 by establishing tolerances for residues of paraquat (1,1'-dimethyl-4,4'-

bipyridinium-ion) derived from application of either the bis (methyl sulfate) or the dichloride salt (both calculated as the cation), in or on the raw agricultural commodities lentils at 0.3 part per million (ppm), lentil forage at 0.1 ppm, and lentil hay at 0.4 ppm.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. A 1-year feeding study in dogs fed diets containing 0, 15, 30, and 50 ppm (equivalent to 0, 0.45, 0.93, and 1.51 milligrams/kilogram (mg/kg) of body weight (bwt) day with a no-observed-effect level (NOEL) of 15 ppm (0.45 mg/kg/day) based on increased severity and extent of chronic pneumonitis in both sexes, especially males, at the 30-ppm dose level.

2. A 23-month chronic feeding/carcinogenicity study in mice fed diets containing 12.5, 37.5, and 100/125 ppm paraquat ion (the highest dose tested (HDT) was increased from 100 to 125 ppm at week 36) with a systemic NOEL of 12.5 ppm (equivalent to 1.87 mg/kg/day) based on renal tubular degeneration in male mice, and weight loss and decreased food intake in female mice. There were no carcinogenic effects observed under the conditions of the study.

3. A 2-year chronic feeding/carcinogenicity study in Fischer rats fed diets containing 0, 1.25, 3.75, and 7.5 mg/kg/day with equivocal (uncertain) evidence of carcinogenicity (squamous cell carcinomas) in the head region (ear, nasal cavity, oral cavity, and skin) of male rats of the highest dose level group, and an approximate systemic NOEL of 1.25 mg/kg/day based on incidence of opacities, cataracts, and nonneoplastic lung lesions (alveolar macrophages and epithelialization and slight peribronchiolar lymphoid hyperplasia). The squamous cell carcinomas were not associated with oral exposure, but were the result of topical exposure (through powdered diet).

4. A 2-year chronic feeding/carcinogenicity study in Wistar rats fed diets containing 6, 30, 100, and 300 ppm (paraquat dichloride) with a systemic NOEL of 100 ppm (equivalent to 5 mg/kg/day) based on increased mortality in males and females; decreased erythrocytes, hemoglobin, and serum protein in males and females; decreased hematocrit, glucose and corpuscular cholinesterase activity in males; decreased leukocytes, albumin-to-globulin ratio, and alkaline phosphatase; increased polymorphonucleocytes in males;

increased potassium and glucose in females; decreased absolute and/or relative weights of heart (males and females), liver and brain (females); and increased absolute weights of kidneys (males and females) at the highest dose tested (HDT) (equivalent to 15 mg/kg/day). There was no evidence of carcinogenicity observed under the conditions of the study.

5. A developmental toxicity study in rats given gavage dosages of 1, 5, and 10 mg paraquat ion/kg of body weight from day 6 through day 15 of pregnancy with NOEL's for fetotoxic effects and maternal toxicity of 1.0 mg/kg/day. The lowest effect level (LEL) was established at 5 mg/kg/day based on weight reduction and slight retardation in ossification (fetotoxicity) and piloerection, weight loss, and hunched appearance (maternal toxicity).

6. A developmental toxicity study in mice given gavage dosages of 1, 5, and 10 mg/kg/day with no developmental toxicity observed under the conditions of the study at any dosage level tested.

7. A three-generation reproduction study with rats fed diets containing 25, 75, and 150 ppm with a systemic NOEL of 25 ppm (equivalent to 1.25 mg/kg/day) based on an increased incidence of alveolar histiocytosis in the lungs of male and female parents. There were no reproductive effects observed under the conditions of the study.

8. Paraquat was negative in 10 mutagenicity studies (mostly gene mutation and chromosome aberration studies and one DNA damage/repair assay); weakly positive in four studies (two gene mutation, one chromosome aberration, and one DNA damage/repair assay); and positive in four studies (all DNA damage/repair assays).

The Agency (Peer Review Committee) initially classified paraquat as a category "C" carcinogen based on the significant increase of squamous cell carcinomas in the head region of the high-dose males in the Fisher rat chronic feeding/carcinogenicity study. Review of the study by an independent laboratory concluded that those tumor sites should not be combined; without the combination, there were no statistically significant tumor increases for any particular tumor type. Discussion and review by the Agency (Peer Review Committee) concluded that these tumor sites normally should not be combined when the exposure to the chemical is by the oral route and that these tumors are likely the result of topical exposure to paraquat contained in the powdered diet (paraquat is a topical irritant), not the result of exposure through the gastrointestinal tract. The Agency considered two additional studies (rat

and mouse carcinogenicity studies) and further evaluated the tumors in the male rats. Based on all the information, the Agency concluded that there is no evidence of carcinogenicity in male Wistar rats at 12 mg/kg/day (HDT) and female Wistar rats at 15 mg/kg/day. The Agency concluded that there was at best equivocal evidence of carcinogenicity in male Fisher rats at 7.5 mg/kg/day and that this equivocal evidence was associated with irritation due to topical exposure, and not with oral exposure. Paraquat was, therefore, placed in Category E (not a human carcinogen). Because paraquat is a restricted-use pesticide and precautionary measures are required to protect applicators from the acute toxicity of the chemical, the potential for carcinogenic effects by excessive (irritating) topical exposure is not a concern for applicators.

The reference dose (RfD) is established at 0.0045 mg/kg body weight/day based on a NOEL of 0.45 mg/kg/day from the 1-year dog study and an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) from existing uses of paraquat utilizes 42% of the RfD for the general U.S. population, or 95.7% of the RfD for children, aged 1 to 6 years old (the population subgroup most highly exposed). The proposed tolerance for lentils would utilize 0.008% of the RfD for the U.S. population, or 0.007% of the RfD for children, aged 1 to 6 years.

The nature of the residue is adequately understood for the purpose of these tolerances. An adequate analytical method is available for enforcement purposes. The analytical method for enforcing these tolerances has been published in the Pesticide Analytical Manual, Vol. II (PAM II). Any secondary residues in milk, eggs, or meat of livestock and poultry will fall within existing tolerances for these commodities.

There are currently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerances be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking

proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 4E4359/P604]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 28, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.205, paragraph (a) is amended in the table therein by adding and alphabetically inserting the raw agricultural commodities lentils, lentil forage, and lentil hay, to read as follows:

§ 180.205 Paraquat; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	*
Lentils	0.3
Lentil, forage	0.1
Lentil, hay	0.4
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[FR Doc. 95-6418 Filed 3-14-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162/P602; FRL-4936-1]

RIN 2070-AC18

Pesticide Tolerances for 2-[1-(Ethoxyimino)Butyl]-5-[2-(Ethylthio)Propyl]-3-Hydroxy-2-Cyclohexen-1-One

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish time limited tolerances for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one (also referred to in this document as sethoxydim) and its metabolites in or on various raw agricultural commodities. The Interregional Research Project No. 4 (IR-4) requested the proposed regulation to establish maximum permissible levels for residues of the herbicide. These time-limited tolerances would expire on December 31, 1996.

DATES: Comments, identified by the document control number [PP 0E3909,

2E4052, 2E4065, 2E4092, and 3E4162/P602], must be received on or before April 14, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8783.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petitions (PP) 0E3909, 2E4052, 2E4065, 2E4092, and 3E4162 to EPA on behalf of the named Agricultural Experiment Stations.

These petitions request that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.412 by establishing time-limited tolerances for combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on certain raw agricultural commodities as follows:

1. *PP 0E3909.* Petition submitted on behalf of the Experimental Stations of Massachusetts, Washington, and